# 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

| SUBMITTER INFORMATION | |
|---|---|
| Name | CareFusion |
| Address | 1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA |
| Phone number | (847) 473-7404 |
| Fax number | (312) 949-0583 |
| Establishment Registration Number | 1423507 OCT 0 3 2013 |
| Name of contact person | Joy Greidanus |
| Date prepared | June 18, 2013 |
| **NAME OF DEVICE** | |
| Trade or proprietary name | AVAflex Vertebral Balloon System |
| Common or usual name | Inflatable Bone Tamp |
| Classification name | Arthroscope |
| Classification panel | Orthopedic |
| Regulation | Class II per 21CFR §888.1100, Procode HRX:<br>Class II per 21CFR §888.3027, Procode NDN: |
| Product Code(s) | TBD |
| Legally marketed device(s) to which equivalence is claimed | CareFusion Inflatable Bone Tamps, K103064, K093463, K090211<br>Radiopaque Bone Cement, K043518 |
| Reason for 510(k) submission | New Device |
| Device description | The Inflatable Bone Tamp (IBT) was designed for use in balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture and preventing cement leakage, while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. |
| Intended use of the device | Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement). |

| SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE | | |
|---|---|---|
| Characteristic | New Device | Predicate<br>CareFusion Vertebral Balloon (K103064) |
| Balloon inflation medium | 60% contrast recommended | 60% contrast recommended |
| Balloon and catheter materials | Polyurethane | Polyurethane |
| Wire mandrel material | Stainless steel | Stainless steel |
| Balloon shape | Cylindrical | Cylindrical |
| Maximum recommended inflation pressure | 400 psi (27 ATM) | 400 psi (27 ATM) |
| Maximum recommended inflation volume | 4 mL – 8 mL | 4 mL – 6mL |

**PERFORMANCE DATA**

**SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

**Performance Test Summary-New Device**

| Characteristic | Standard/Test/FDA Guidance | Results Summary |
|---|---|---|
| Inflation pressure | Constrained burst test | The balloon catheters exceeded the requirements for the minimum burst pressure in a constrained environment |
| Inflation volume | Unconstrained burst test | The balloon catheters exceeded the requirements for the minimum burst volume in an unconstrained environment |
| Balloon double wall thickness | Calibrated measurement | The double wall thickness of the balloons was substantially equivalent to that of the predicate device |

**SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION**

N/A – No clinical tests were conducted for this submission

**CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA**

The results of the non-clinical tests show that the CareFusion Flexible IBT System meets or exceeds all performance requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

CareFusion
Ms: Joy Greidanus
Manager, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K131824
Trade/Device Name: Inflatable Bone Tamp
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: August 28, 2013
Received: August 29, 2013

Dear Ms. Greidanus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131824



*1500 Waukegan Road*
*McGaw Park, Illinois 60085-6787*
*847.473.7404*
*FAX: 847.473.7790*

510(k) Number (if known): Unknown at this time

Device Name: Inflatable Bone Tamp

**Indications For Use:**

Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

Prescription Use __X__ (Per 21 CFR 801 Subpart D)
And/Or Over-The Counter Use_____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131824